SHERMAN J. SILBER, M.D., F.A.C.S.
INFERTILITY CENTER OF ST. LOUIS

St. Luke's Hospital Medical Building
224 S. Woods Mill Road, Suite 730
Saint Louis, Missouri USA 63017
(314) 576-1400 • Fax: (314) 576-1442

December 22, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane Room 1061
Rockville, MD 20852

Re: Docket #97N-48S, Suitability Determination for Donors of Human Cellular and Tissue Based Products

To whom it may concern:

I have been made aware of the proposed rules regulating donor oocyte procedures, and although most of them are acceptable, there are some that are completely unacceptable. The most objectionable rule is the requirement to test an oocyte donor before the donor oocyte cycle, and then freeze the embryos and quarantine them for six months until the oocyte donor can be retested for infectious diseases. The proposed rule indicates only then are the embryos "suitable for embryo transfer."

There is no evidence that ooctyes, embryos, or isolated sperm cells used with in-vitro fertilization (IVF) and embryo transfer (ET) are vectors of the diseases listed in the FDA proposal. There is also no scientific evidence documenting transmission of HIV and other infectious diseases from in-vitro fertilization or embryo transfer, and to the best of anyone's knowledge, there have been no cases of HIV contracted from IVF in the past twenty-one years.

The proposed quarantining of embryos will significantly increase the costs and number of cycles needed to achieve the same pregnancy rate. Quarantining embryos will also decrease the success rate for patients undergoing donor oocyte IVF by approximately 50 percent. Unnecessary death of embryos will also occur, and it has been estimated that there may be as many as 9,000 embryo deaths per year representing a terrible loss of biological material and potential human lives. The prolonged delay of embryo transfer will also cause unnecessary anxiety in the patient, as well as potential health risks of delaying childbirth in an already older woman.

By attempting to require the quarantining of embryos resulting from donor oocyte IVF, the FDA is interfering with the practice of medicine. There seems to be no understanding by the FDA that using semen carries with it a much different risk for transmission of disease than the hypothetical risk associated with the use of isolated oocytes and embryos. The basis for these regulations clearly lacks any scientific evidence, and since my clinic, as well as many other reputable clinics, have been performing these procedures for many years without problem or incident, we must object to this unnecessary intrusion into our medical practice.

Sincerely,

Sherman J. Silber, M.D.

SJS/dec

P.S. Furthermore, the role of the FDA is NOT to regulate the practice of medicine. That is clearly not in their legal jurisdiction. Their only role is to regulate the availability of pharmaceuticals on the shelf. They have no legal or scientific authority to impose these restrictions. The increase in embryo deaths resulting from such a proposal would also result in a political disaster.

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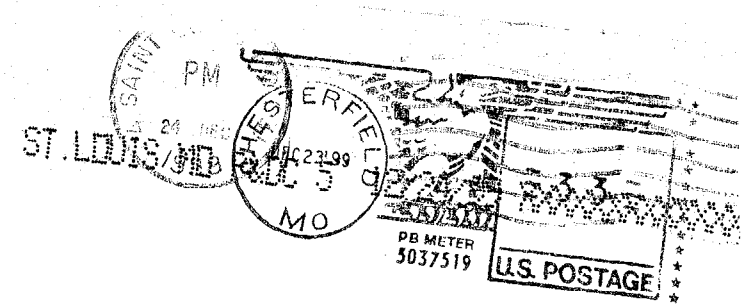

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